UNITED STATES DISTRICT COURT
IN THE SOUTHERN DISTRICT OF NEW YORK

EMA AYMINSKY, Plaintiff, v. MERCK & CO., INC., and PROCTER & GAMBLE PHARMACEUTICALS, INC., and AVENTIS PHARMACEUTICALS, INC. Defendants.	)	Civil Action No. 1:08cv1019 (JFK) ECF CASE **COMPLAINT AND JURY DEMAND**

COMPLAINT

Comes now Plaintiff, EMA AYMINSKY, by and through her undersigned attorney, and for Plaintiff's causes of action against Merck & Co. Inc. ("Merck"), Procter & Gamble Pharmaceuticals, Inc. ("Procter & Gamble") and Aventis Pharmaceuticals, Inc., ("Aventis") (also collectively "Defendants") alleges and state as follows:

INTRODUCTION

1) Plaintiff files this action for personal injury suffered as a result of ingesting defective and dangerous osteoporosis drugs, including Merck's drug Fosamax and Procter & Gamble and Aventis' drug Actonel, that were designed, researched, manufactured, labeled, packaged, promoted marketed, and/or sold by Defendants.

2) Plaintiff has filed this lawsuit within any applicable statute of limitations period. Plaintiff acted with diligence and could not have brought a cause of action against any of the named Defendants until Plaintiff discovered that the claimed injury was a result of the action and/or omissions of Defendants

3) The drugs that Plaintiff ingested were defective and unreasonably dangerous because they were not reasonably safe for their intended use, they subjected Plaintiff to risks that exceeded their benefits, they were defective in design and formulation thereby making them more dangerous than an ordinary consumer would expect, their risks exceeded those associated with the medical conditions for which they were prescribed, and because the drugs were otherwise defective and unreasonably dangerous as set forth herein.

4) Before the Plaintiff was prescribed and ingested the Defendants knew or should have known that the drugs were associated with serious and/or life threatening side effects that were not properly disclosed to prescribers or users. The Defendants had an obligation under the law to disclose all significant risks associated with their products.

5) Due to the Defendants failure to adequately warn the FDA, doctors, and consumers of the known risks associated with their drugs, Plaintiff's physicians were unable to inform Plaintiff and Plaintiff was unaware of the true risks associated with ingesting the drugs. These risks were known or should have been known by Defendants at the time that they marketed the drugs to the public based on, among other things, adverse event reports, clinical studies and the medical evidence of dangerous and potentially fatal side effects from the use of the drugs in the United States and elsewhere. The Defendants did not, however, conduct adequate testing to establish the safety of the drugs before marketing them nor did the Defendants perform adequate post-marketing surveillance and monitoring, which would have otherwise prevented Plaintiff's injuries. Rather, the Defendants aggressively marketed the drugs and promoted their use while downplaying and/or obfuscating evidence of serious and potentially fatal side effects.

6) Plaintiff has incurred injuries and damages caused by the use of the drugs Fosamax and Actonel which were manufactured and marketed by Defendants.

JURISDICTION AND VENUE

7) This Court has jurisdiction over this action pursuant to28 U.S.C. § 1332. There is complete diversity of citizenship between the Plaintiff and Defendants and the amount in controversy exceeds $75,000.00, exclusive of interest and costs. Defendant Merck sells and markets Fosamax in the State of New York and otherwise regularly conducts business in the state. Defendants Procter & Gamble and Aventis sell and market Actonel in the State of New York and otherwise regularly conduct business in the state.

8) Venue is proper within this district and division pursuant to Conditional Management Order No. 3., whereby Defendant has stipulated and agreed to not assert any objection as to improper venue and this Court has allowed direct filing of cases into the Southern District of New York.

PARTIES

9) Plaintiff is a resident of Falls Church, Virginia.

10) Defendant Merck & Co. Inc., is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business in New Jersey. The Defendant's registered office is at 820 Bear Tavern Road, City of West Trenton, Mercer County, New Jersey.

11) At all times relevant herein, Defendant Merck was in the business of researching, designing, testing, monitoring, manufacturing, labeling, advertising, marketing,

promoting, selling and distributing pharmaceuticals, including Fosamax, and other products in the State of Virginia for use and consumption by citizens of Virginia, including Plaintiff.

12) Defendant Procter & Gamble, is a corporation organized and existing under the laws of Ohio with its principal place of business in Ohio. Procter & Gamble's registered office is at One Procter Gamble Plaza, Cincinnati, Ohio.

13) At all times relevant herein, Defendant Procter & Gamble was in the business of researching, designing, testing, monitoring, manufacturing, labeling, advertising, marketing, promoting, selling and distributing pharmaceuticals, including Actonel, and other products in the State of Virginia for use and consumption by citizens of Virginia, including Plaintiff.

14) Defendant Aventis, is a corporation organized and existing under the laws of Delaware with its principal place of business in New Jersey. Aventis registered office is at 200 Crossing Boulevard, Bridgewater, New Jersey 08807.

15) At all times relevant herein, Defendant Aventis was in the business of researching, designing, testing, monitoring, manufacturing, labeling, advertising, marketing, promoting, selling and distributing pharmaceuticals, including Actonel, and other products in the State of Virginia for use and consumption by citizens of Virginia, including Plaintiff. \

FACTUAL BACKGROUND

16) Defendant, Merck, is the designer, manufacturer, marketer, and distributor of Fosamax, a drug used primarily to alleviate or reverse the effects of osteoporosis and Paget's disease.

17) In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's alendronate, an oral bisphosphonate, for various uses, including the treatment of osteoporosis. *Alendronate* is marketed by Merck under the name Fosamax.

18) Defendants Procter and Gamble and Aventis designed, tested, developed, marketed, distributed and sold Actonel, a drug used primarily to alleviate or reverse the effects of osteoporosis.

19) In April 2000, the FDA approved Procter & Gamble and Aventis' *risedronate*, an oral bisphosphonate, for various uses, including the treatment of osteoporosis. *Risedronate* is marketed by Procter & Gamble and Aventis under the name Actonel.

20) Bisphosphonates are used for treating bone conditions. Fosamax and Actonel fall within a class of drugs known as nitrogenous bisphosphonates which also include drugs such as Aredia and Zometa, which are administered intravenously for chemotherapy and adjunct chemotherapy but are not indicated for the use in non-cancerous conditions.

21) There are two classes of bisphosphonates: the N containing (nitrogenous) and non-N containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); alendronate (Fosamax); and risedronate (Actonel). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate and Risedronate contain a nitrogen atom.

22) Numerous medical articles and studies, in the 1990's and 2000's, reported the frequent occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As a result, Defendants knew or should have known that Fosamax and

Actonel, shared a similar likelihood to cause the disease as the other drugs within its specific subclass of bisphosphonates.

23) Defendants knew or should have known that bisphosphonates, including Fosamax and Actonel, inhibit endothelial cell function. Similarly, Defendants knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

24) Defendants also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can result in a non-healing wound. That in turn can progress to widespread necrosis (bone death and osteomyelitis (inflammation of bone marrow).

25) Osteonecrosis of the Jaw ("ONJ") is a disfiguring and disabling condition through which the jaw bones suffer bone death and rotting of the bone. The disease typically is manifested by loosening of teeth, lesions on the gums and osteomyelitis – inflammation of bone marrow.

26) Osteonecrosis of the jaw is a serious medical diagnosis and can result in extreme pain, severe disability, and death. Once the osteonecrosis becomes symptomatic, it is very difficult to treat and typically is not reversible.

27) Dentists and oral surgeons are now being advised by dental associations to refrain from any invasive procedure (such as drilling a cavity) for any patient on bisphosphonate medications, including Fosamax and Actonel.

28) Following the release of these medications the FDA has received a significant number of reports of ONJ among users of both Fosamax and Actonel.

29) On or about August 25, 2004, the FDA posted its Postmarketing Safety Review on bisphosphonates, which indicated that the risk of osteonecrosis of the jaw was not confined to those drugs used for chemotherapy and extended to the oral bisphosphonates.

30) As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonates.

31) Defendants knew of the significant risk of dental and oral complications caused by ingestion of their bisphosphonate drugs but failed to adequately and sufficiently warn consumers, including Plaintiff, or the medical community, of such risks.

32) As a direct and proximate result, Plaintiff was prescribed Fosamax and Actonel and has been permanently and severely injured, having suffered serious consequences from the ingestion of these drugs. Plaintiff requires and will in the future require ongoing medical care and treatment.

33) Plaintiff has suffered from mental anguish from the knowledge that she will have life long complications as a result of the injuries Plaintiff sustained from the ingestion of Fosamax and Actonel.

34) Plaintiff, Ema Ayminsky, was prescribed Fosamax from June 1999 until November 2001 in order to help alleviate the effects of her osteoporosis.

35) Plaintiff used Fosamax as prescribed and in a foreseeable manner.

36) Plaintiff used Fosamax which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

37) Plaintiff was prescribed Actonel from December 2001 until April 2006 in order to alleviate the effects of her osteoporosis

38) Plaintiff used Actonel as prescribed and in a foreseeable manner.

39) Plaintiff used Actonel which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

40) As a direct and proximate result of using Fosamax and Actonel, Plaintiff suffered osteonecrosis of her jaw.

41) Plaintiff, as a direct and proximate result of using Fosamax and Actonel, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

42) Plaintiff would not have used Fosamax nor Actonel had Defendants properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

43) The running of any statute of limitation has been tolled by reason of the Defendants fraudulent conduct. The Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's prescribing physicians the true risks associated with taking Fosamax and Actonel.

44) As a result of the Defendants actions, Plaintiff and Plaintiff's prescribing physicians were unaware, and could not reasonably know or have learned through reasonable

diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the Defendants acts and omissions.

45) Furthermore, the Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the truth, quality and nature of their bisphosphonate medications. Defendants were under a duty to disclose the true character, quality and nature of their drugs because this was a non-public information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, medical providers and/or to health facilities. In addition, the Defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.

46) The Plaintiff had no knowledge that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. The Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting profitable drugs, notwithstanding the known or reasonably known risks. Plaintiff and his/her medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendants representations.

COUNT I
NEGLIGENCE
(against Defendants Merck, Procter & Gamble and Aventis)

47) Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

48) Defendant, Merck, is the designer, manufacturer, and seller of the drug Fosamax.

49) When placed in the stream of commerce in 1995, Fosamax was not accompanied by adequate warnings regarding the significant oral and dental risks associated with the ingestion of Fosamax, particularly osteonecrosis of the jaw. The warnings, given by the Defendant Merck did not accurately reflect the existence of the risk, let alone the incidence, symptoms, scope or severity of such injuries.

50) Merck failed to perform adequate testing concerning the safety of the drug Fosamax in that adequate testing would have shown that Fosamax poses serious risk of dental, oral, and jaw problems which would have permitted appropriate warnings to have been given by Merck to prescribing physicians, insurance companies, and the consuming public.

51) Merck had a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing and selling Fosamax, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

52) Defendants, Procter & Gamble and Aventis, are the designer, manufacturer, and seller of the drug Actonel.

53) When placed in the stream of commerce in 2000, Actonel was not accompanied by adequate warnings regarding the significant oral and dental risks associated with the ingestion of Actonel, particularly osteonecrosis of the jaw. The warnings, given by Procter & Gamble and Aventis did not accurately reflect the existence of the risk, let alone the incidence, symptoms, scope or severity of such injuries.

54) Procter & Gamble and Aventis failed to perform adequate testing concerning the safety of the drug Actonel in that adequate testing would have shown that Actonel poses serious risk of dental, oral, and jaw problems which would have permitted appropriate warnings to have been given by Procter & Gamble and Aventis to prescribing physicians, insurance companies, and the consuming public.

55) Procter & Gamble and Aventis had a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing and selling Actonel, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

56) Defendants were negligent in the design, manufacturing, testing, advertising, marketing, promotion, labeling, and sale of Fosamax and Actonel in that, among other things the Defendants:

a. Failed to use reasonable care to design a nitrogenous bisphosphonate that was safe for its intended and foreseeable uses, not defective, and not unreasonably dangerous;

b. Recklessly, falsely, and deceptively represented or knowingly omitted, suppressed, and/or concealed material facts regarding the safety and efficacy from physicians, the medical community, health insurers, and state formularies;

c. Negligently marketed Fosamax and Actonel despite the fact that risks of the drug were so high and the benefits so speculative that no reasonable pharmaceutical company, exercising due care, would have done so;

d. Failed to use reasonable care to make the necessary tests, inspections, drug trials, and/or evaluations to discover defects and unreasonably dangerous conditions;

e. Failed to comply with and use reasonable care to comply with standards of care including accepted industry standards, FDA recommendations, government regulations, in the affixing of warnings and otherwise production and distribution of Fosamax and Actonel;

f. Failed to use reasonable care to warn Plaintiff of dangers known and/or reasonably suspected;

g. Failed to timely use reasonable care to discover the dangerous conditions or character of Fosamax and Actonel;

h. Failed to issue proper warnings regarding all possible adverse side effects and the comparative severity and duration of such effects, despite the fact that the defendants knew, or should have known, that numerous case reports, adverse even reports and other data associated with osteonecrosis of the jaw and other oral and dental problems;

i. Failed to conduct adequate pre-clinical testing and post-marketing surveillance.

57) Despite the fact that Defendants knew or should have known of the unreasonable, dangerous side effects which many users would be unable to remedy by any means, the Defendants continue to market Fosamax and Actonel to consumers including the Plaintiff.

58) Defendants knew or should have known that consumers, such as Plaintiff, would forseeably suffer injury as a result of defendants failure to exercise ordinary care as described above.

59) Defendants negligence was a direct and proximate cause of the harm suffered by the Plaintiff.

60) As a direct and proximate cause and legal result of the Defendants negligence, carelessness, and other wrongdoing, the Plaintiff has suffered physical personal injury, including but not limited to, being diagnosed with osteonecrosis of the jaw, medical expenses, future medical expense, diminished capacity for the enjoyment of life, increased risk of premature death, and other financial expenses and economic losses.

61) Defendants conduct as described herein was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby, entitling Plaintiff to punitive damages.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor and against Defendants in a sum in excess of the jurisdictional requirement of this Court; for Plaintiff's costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT II
FRAUDULENT MISREPRESENTATION
(against Defendants Merck, Procter & Gamble and Aventis)

62) Plaintiff restates the allegations set forth in the paragraphs above as if fully set forth herein.

63) Defendant, Merck made fraudulent misrepresentations with respect to Fosamax and in that, among other things:

a. Merck represented through advertising, marketing, labeling, publications, and submissions that Fosamax had been tested and found to be safe and effective for the treatment of osteoporosis and Paget's disease;

b. Merck represented that Fosamax was safer than other alternative medications that were on the market.

64) Merck knew that these representations were false, yet willfully and recklessly disregarded its obligation to make truthful representations regarding the safety and risks of Fosamax to Plaintiff, other consumers, and the medical community.

65) The representations were made by Merck with the intention of inducing consumers, like Plaintiff, to act upon them and purchase Fosamax.

66) Merck's representations were made with the intent of deceiving Plaintiff, and other consumers, in order to maximize profit and encourage the sale of Fosamax.

67) Plaintiff did in fact rely upon the statements and representations.

68) Defendants, Procter & Gamble and Aventis made fraudulent misrepresentations with respect to Actonel in that, among other things:

a. Procter & Gamble and Aventis represented through advertising, marketing, labeling, publications, and submissions that Actonel had been tested and found to be safe and effective for the treatment of osteoporosis;

b. Procter & Gamble and Aventis represented that Actonel was safer than other alternative medications that were on the market.

69) Procter & Gamble and Aventis knew that these representations were false, yet willfully and recklessly disregarded its obligation to make truthful representations regarding the safety and risks of Actonel to Plaintiff, other consumers, and the medical community.

70) The representations were made by Procter & Gamble and Aventis with the intention of inducing consumers, like Plaintiff, to act upon them and purchase Actonel.

71) Procter & Gamble and Aventis' representations were made with the intent of deceiving Plaintiff, and other consumers, in order to maximize profit and encourage the sale of Actonel.

72) Plaintiff did in fact rely upon the statements and representations.

73) As a direct and proximate cause and legal result of the Defendants negligence, carelessness, and the other wrongdoing and actions of the defendants as described herein, Plaintiff has suffered physical personal injury, including but not limited to, being diagnosed with osteonecrosis of the jaw, medical expenses, future medical expense, diminished capacity for the enjoyment of life, increased risk of premature death and other losses and damages.

74) Defendants conduct, as described herein, was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of Plaintiff and other consumers, thereby entitling Plaintiff to punitive damages.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor and against Defendants in a sum in excess of the jurisdictional requirement of this Court; for Plaintiff's costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT III
FRAUDULENT CONCEALMENT
(against Defendants Merck, Procter & Gamble and Aventis)

75) Plaintiff restates the allegations set forth in the paragraphs above as if fully set forth herein.

76) Merck fraudulently concealed information with respect to Fosamax, in that among other things:

a. Merck represented through advertising, marketing, labeling, publications and submissions that Fosamax was safe and fraudulently withheld and concealed information about the substantial risks of using Fosamax;

b. Merck represented that Fosamax was safer than other alternative medications and fraudulently concealed information which demonstrated that Fosamax was not safer than alternatives available on the market.

77) Defendant solely had access to material facts with regard to the dangers and unreasonable risks of Fosamax.

78) Merck intentionally concealed information about the risks of Fosamax, and the representations made were known by Merck to be false.

79) The concealment of information and the misrepresentation about Fosamax were made by Merck with the intent that consumers, including Plaintiff, would rely upon them in purchasing Fosamax.

80) Plaintiff did in fact rely upon the representations and were unaware of the substantial dental and oral risks of Fosamax, including osteonecrosis of the jaw, which Merck concealed from Plaintiff.

81) Procter & Gamble and Aventis fraudulently concealed information with respect to Actonel, in that among other things:

a. Procter & Gamble and Aventis represented through advertising, marketing, labeling, publications and submissions that Actonel was safe and fraudulently withheld and concealed information about the substantial risks of using Actonel;

b. Procter & Gamble and Aventis represented that Actonel was safer than other alternative medications and fraudulently concealed information which demonstrated that Actonel was not safer than alternatives available on the market.

82) Procter & Gamble and Aventis had sole access to material facts with regard to the dangers and unreasonable risks of Actonel.

83) Procter & Gamble and Aventis intentionally concealed information about the risks of Actonel, and the representations made were known by Procter & Gamble and Aventis to be false.

84) The concealment of information and the misrepresentation about Actonel were made by Procter & Gamble and Aventis with the intent that consumers, including Plaintiff, would rely upon them in purchasing Actonel.

85) Plaintiff did in fact rely upon the representations and were unaware of the substantial dental and oral risks of Actonel, including osteonecrosis of the jaw, which Procter & Gamble and Aventis concealed from Plaintiff.

86) As a direct and proximate cause and legal result of the Defendants negligence, carelessness, and the other wrongdoing and actions of the Defendants, as described herein,

Plaintiff has suffered physical personal injury, including but not limited to, being diagnosed with osteonecrosis of the jaw, medical expenses, future medical expense, diminished capacity for the enjoyment of life, increased risk of premature death and other losses and damages.

87) Defendants conduct, as described herein, was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of Plaintiff and other consumers, thereby entitling Plaintiff to punitive damages.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in Plaintiff's favor and against Defendants in a sum in excess of the jurisdictional requirement of this Court; for Plaintiff's costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT IV
PRODUCTS LIABILITY – FAILURE TO WARN
(against Defendants Merck, Procter & Gamble and Aventis)

88) Plaintiff restates the allegations set forth in the paragraphs above as if fully set forth herein.

89) Defendants, as manufacturers of pharmaceuticals, had a duty to warn of adverse drug reactions, which they know or have reason to know, are inherent in the use of its pharmaceutical products.

90) Defendant, Merck, failed to adequately warn Plaintiff, Plaintiff's physicians and the general public of the risks of Fosamax being used by Plaintiff.

91) Merck failed to adequately warn of dangers inherent with the use of Fosamax and Merck's misrepresentations and inadequate disclosures to the Plaintiff's physicians, Plaintiff, and the general public, made the product unreasonably dangerous for normal use.

92) Merck is liable in tort to the Plaintiff upon the grounds that:

a. Fosamax was unsafe, defective and unreasonably dangerous for its intended and/or foreseeable uses, by reason of inadequately warning and/or inadequately communicating warnings.

b. In distributing, promoting and selling Fosamax not accompanied by adequate warnings of the dangers that were known or should have been known; by failing to provide adequate warnings regarding all known or reasonably knowable potential side effects associated with the use of Fosamax, and the comparative nature, extent, severity, incidence and duration of such adverse effects; failing to provide adequate warnings regarding the signs, symptoms, incidence, scope or severity of the side effects, and/or identify appropriate testing, monitoring and/or remedial action; failing to provide adequate warnings in a timely manner and information necessary for their purposes, thus placing the Plaintiff and consuming public at risk;

c. Defendant was aware that Fosamax would be used without inspection and study for the defects inherent in Fosamax as alleged, and that given the resources of the Plaintiff and his/her physicians, any reasonably anticipated inspection would have failed to detect the defects;

d. Defendant expected and knew that Fosamax would reach the consuming public and Plaintiff. Fosamax was, in fact, received by Plaintiff without change in the condition in which the drug and its labeling was first manufactured and sold.

e. Plaintiff was a foreseeable user of the product in its intended manner and suffered serious harm because of said use.

93) Defendants, Procter & Gamble and Aventis, failed to adequately warn Plaintiff, Plaintiff's physicians and the general public of the risks of Actonel being used by Plaintiff.

94) Procter & Gamble and Aventis failed to adequately warn of dangers inherent with the use of Actonel and Procter & Gamble and Aventis' misrepresentations and inadequate disclosures to the Plaintiff's physicians, Plaintiff, and the general public, made the product unreasonably dangerous for normal use.

95) Procter & Gamble and Aventis are liable in tort to the Plaintiff upon the grounds that:

a. Actonel was unsafe, defective and unreasonably dangerous for its intended and/or foreseeable uses, by reason of inadequately warning and/or inadequately communicating warnings.

b. In distributing, promoting and selling Actonel not accompanied by adequate warnings of the dangers that were known or should have been known; by failing to provide adequate warnings regarding all known or reasonably knowable potential side effects associated with the use of Actonel, and the comparative nature, extent, severity, incidence and duration of such adverse effects; failing to provide adequate warnings regarding the signs, symptoms, incidence, scope or severity of the side effects, and/or identify appropriate testing, monitoring and/or remedial action; failing to provide adequate warnings in a timely manner and

information necessary for their purposes, thus placing the Plaintiff and consuming public at risk;

c. Procter & Gamble and Aventis were aware that Actonel would be used without inspection and study for the defects inherent in Actonel as alleged, and that given the resources of the Plaintiff and his/her physicians, any reasonably anticipated inspection would have failed to detect the defects;

d. Procter & Gamble and Aventis expected and knew that Actonel would reach the consuming public and Plaintiff. Actonel was, in fact, received by Plaintiff without change in the condition in which the drug and its labeling was first manufactured and sold.

e. Plaintiff was a foreseeable user of the product in its intended manner and suffered serious harm because of said use.

96) The Fosamax and Actonel manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings and/or instructions because, after the Defendants knew or should have known of the risks of injury from the use of bisphosphonate medications, they failed to provide adequate warnings to consumers of the product.

97) As a direct and proximate cause and legal result of the Defendants negligence, carelessness, and the other wrongdoing and actions of the Defendants as described herein, Plaintiff has suffered physical personal injury, including but not limited to, being diagnosed with osteonecrosis of the jaw, medical expenses, future medical expense, diminished capacity for the enjoyment of life, increased risk of premature death and other losses and damages.

98) Defendants conduct, as described herein, was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of Plaintiff and other consumers, thereby entitling Plaintiff to punitive damages.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor and against Defendants in a sum in excess of the jurisdictional requirement of this Court; for Plaintiff's costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT V
PRODUCTS LIABILITY – DESIGN DEFECT
(against Defendants Merck, Procter & Gamble and Aventis)

99) Plaintiff restates the allegations set forth in the paragraphs above as if fully set forth herein.

100) The Fosamax manufactured and/or supplied by Merck was placed into the stream of commerce in a defective and unreasonably unsafe condition in that the foreseeable risks of its use exceeded the benefits associated with the design or formulation.

101) Merck knew or should have known at the time of manufacture that Fosamax was defective in design or formulation and that Fosamax created a risk of harm to consumers such as Plaintiff when used in the way it was intended to be used and in a manner which was reasonably foreseeable by Merck.

102) The Fosamax manufactured and/or supplied by Merck was placed into the stream of commerce when they knew or should have known of the defective design or formulation and a reasonable person would have concluded that the utility of Fosamax did not outweigh the risk inherent in marketing Fosamax designed in that manner.

103) As set forth in this complaint and otherwise, Merck knew of Fosamax defective nature at the time of its manufacture, but continued to design, manufacture, market, promote, represent to the consuming public, prescribers, and Plaintiff that Fosamax was safe for the sole purpose of maximizing sales and profits at the expense of the public health and safety in conscious disregard of foreseeable harm caused by Fosamax.

104) The Actonel manufactured and/or supplied by Procter & Gamble and Aventis was placed into the stream of commerce in a defective and unreasonably unsafe condition in that the foreseeable risks of its use exceeded the benefits associated with the design or formulation.

105) Procter & Gamble and Aventis knew or should have known at the time of manufacture that Actonel was defective in design or formulation and that Actonel created a risk of harm to consumers such as Plaintiff when used in the way it was intended to be used and in a manner which was reasonably foreseeable by Procter & Gamble and Aventis.

106) The Actonel manufactured and/or supplied by Procter & Gamble and Aventis was placed into the stream of commerce when they knew or should have known of the defective design or formulation and a reasonable person would have concluded that the utility of Actonel did not outweigh the risk inherent in marketing Actonel designed in that manner.

107) As set forth in this complaint and otherwise, Procter & Gamble and Aventis knew of Actonel's defective nature at the time of its manufacture, but continued to design, manufacture, market, promote, represent to the consuming public, prescribers, and Plaintiff that Actonel was safe for the sole purpose of maximizing sales and profits at the expense of the public health and safety in conscious disregard of foreseeable harm caused by Actonel.

108) As a direct and proximate cause and legal result of the Defendants negligence, carelessness, and the other wrongdoing and actions of the Defendants as described herein, Plaintiff has suffered physical personal injury, including but not limited to, being diagnosed with osteonecrosis of the jaw, medical expenses, future medical expense, diminished capacity for the enjoyment of life, increased risk of premature death and other losses and damages.

109) Defendants conduct, as described herein, was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of Plaintiff and other consumers, thereby entitling Plaintiff to punitive damages.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor and against Defendants in a sum in excess of the jurisdictional requirement of this Court; for Plaintiff's costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT VI
BREACH OF EXPRESS WARRANTY
(against Defendants Merck, Procter and Gamble and Aventis)

110) Plaintiff restates the allegations set forth in the paragraphs above as if fully set forth herein.

111) Merck expressly represented to Plaintiff, and other consumers, physicians, and the medical community at large, that Fosamax was safe and fit for its intended purposes, that it did not produce dangerous side effects, and that it was adequately tested prior to being marketed and sold.

112) Fosamax does not conform to these express representations because Fosamax is not safe and has serious, life-threatening side effects.

113) Consumers, including Plaintiff Ema Ayminsky, reasonably relied upon Defendant's express warranties.

114) Procter & Gamble and Aventis expressly represented to Plaintiff, and other consumers, physicians, and the medical community at large, that Actonel was safe and fit for its intended purposes, that it did not produce dangerous side effects, and that it was adequately tested prior to being marketed and sold.

115) Actonel does not conform to these express representations because Actonel is not safe and has serious, life-threatening side effects.

116) Consumers, including Plaintiff Ema Ayminsky reasonably relied upon Procter & Gamble's and Aventis' express warranties.

117) As a direct and proximate cause and legal result of Defendants negligence, carelessness, and the other wrongdoing and actions of the defendant as described herein, Plaintiff has suffered physical personal injury, including but not limited to, being diagnosed with osteonecrosis of the jaw, medical expenses, future medical expense, diminished capacity for the enjoyment of life, increased risk of premature death and other losses and damages.

118) Defendants conduct, as described herein, was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of Plaintiff and other consumers, thereby entitling Plaintiff to punitive damages.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor and against Defendants in a sum in excess of the jurisdictional requirement of this

Court; for Plaintiff's costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT VII
BREACH OF IMPLIED WARRANTY
(against Defendants Merck, Procter and Gamble and Aventis)

119) Plaintiff restates the allegations set forth in the paragraphs above as if fully set forth herein.

120) At the time Merck marketed, sold and distributed Fosamax for use by Plaintiff, Merck knew of the use for which Fosamax was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

121) Merck was aware that consumers, including Plaintiff, would ingest Fosamax for the treatment of osteoporosis and for other purposes.

122) Plaintiff reasonably relied upon the skill, judgment, and sensibility of Merck as to whether Fosamax was of merchantable quality and safe and fit for its intended use.

123) Merck breached its implied warranty to Plaintiff in that Fosamax was not of merchantable quality or safe for its intended use, because Fosamax was and is unreasonably dangerous and unfit for the ordinary purposes for which it was used.

124) Fosamax reached consumers, including Plaintiff, without substantial change in the condition it was manufactured or sold by Merck.

125) At the time Procter & Gamble and Aventis marketed, sold and distributed Actonel for use by Plaintiff, Procter & Gamble and Aventis knew of the use for which Actonel was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

126) Procter & Gamble and Aventis were aware that consumers, including Plaintiff, would ingest Actonel for the treatment of osteoporosis and for other purposes.

127) Plaintiff reasonably relied upon the skill, judgment, and sensibility of Procter & Gamble and Aventis as to whether Actonel was of merchantable quality and safe and fit for its intended use.

128) Procter & Gamble and Aventis breached its implied warranty to Plaintiff in that Actonel was not of merchantable quality or safe for its intended use, because Actonel was and is unreasonably dangerous and unfit for the ordinary purposes for which it was used.

129) Actonel reached consumers, including Plaintiff, without substantial change in the condition it was manufactured or sold by Procter & Gamble and Aventis.

130) As a direct and proximate cause and legal result of the Defendants negligence, carelessness, and the other wrongdoing and actions of the defendant as described herein, Plaintiff has suffered physical personal injury, including but not limited to, being diagnosed with osteonecrosis of the jaw, medical expenses, future medical expense, diminished capacity for the enjoyment of life, increased risk of premature death and other losses and damages.

131) Defendants conduct, as described herein, was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of Plaintiff and other consumers, thereby entitling Plaintiff to punitive damages.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor and against Defendants in a sum in excess of the jurisdictional requirement of this Court; for Plaintiff's costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

COUNT VIII
UNJUST ENRICHMENT
(against Defendants Merck, Procter and Gamble, and Aventis)

132) Plaintiff restates the allegations set forth in the paragraphs above as if fully set forth herein.

133) As a direct, proximate, and foreseeable result of Defendants acts and otherwise wrongful conduct, Plaintiff was gravely harmed. Defendants profited and benefited from the sale of Fosamax and Actonel, even as it injured Plaintiffs.

134) Defendants have voluntarily accepted and retained these profits and benefits derived from consumers, including Plaintiff, with full knowledge and awareness that, as a result of Defendants unconscionable and intentional wrongdoing, consumers, including Plaintiff, were not receiving products of the quality, nature, fitness, or value that had been represented by Defendants, or that reasonable consumers expected. Plaintiff purchased and ingested medicine expected would improve her health, and instead found her health destroyed.

135) By virtue of the conscious wrongdoing alleged in this Complaint, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants wrongful profits, revenue, and benefits, to the extent, and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants unjust enrichment.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor and against Defendants in a sum in excess of the jurisdictional requirement of this Court; for Plaintiff's costs herein incurred; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried by a jury.

PUNITIVE AND/OR EXEMPLARY DAMAGES

136) Clear and convincing evidence exists that the above described actions of Defendants Merck, Procter & Gamble and Aventis were committed oppressively, fraudulently, or with malice or gross negligence. Therefore, Plaintiff specifically requests that the Court submit jury questions on issues of Defendants conduct to support Punitive and/or Exemplary Damages in the maximum amount allowed by Virginia law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief from Defendants as follows:

Four Million Dollars ($4,000,000.00) in compensatory damages, for personal injuries incurred as a result of ingesting Fosamax and Actonel, including but not limited to, being diagnosed with osteonecrosis of the jaw, including but not limited to past medical expenses, future and continuing medical expenses, loss of earning capacity, pain and suffering, mental anguish, ancillary associated expenses, refund of the cost of purchasing Fosamax and Actonel, plus costs of this action with interest on said judgment at the rate prescribed by applicable law from the date of diagnosis together with any other costs and expenses in connection therewith. Plaintiff further demands judgment against Defendants for punitive damages in the amount of Four Million Dollars ($4,000,000.00), together with interest, and all such other relief as the Court deems proper.

Respectfully submitted,

_____/s/_____
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108 Railroad Avenue
Orange, VA 22960
540-672-4224
540-672-3055 – Fax
Counsel for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff herewith requests a trial by jury as to all issues of material fact.

Dated:

THE MILLER FIRM, LLC

By: _____/s/_____

Michael J. Miller, Esquire (VSB 19171)
David J. Dickens, Esquire (VSB 72891)
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